

REQUEST FOR PROPOSALS

Performance Audit Services
CIRM RFP
20/21 CIRM 101

January 4, 2021

The California Institute for Regenerative Medicine invites interested bidders to review and respond to this Request for Proposals (RFP), entitled RFP 20/21 CIRM 101 2019-20 Fiscal Year Performance Audit Services for the California Institute for Regenerative Medicine (CIRM). The RFP seeks Performance Auditing services for the fourth triennial performance audit of the CIRM's functions, operations, management systems, and policies and procedures for 2019-2020 fiscal year .

Prospective bidders interested in responding to this RFP are encouraged to email the contact person listed below by January 15, 2021, indicating their interest with the firm's name, address, and email address where future notifications can be sent. Submitting the email will ensure that your firm receives supplemental or updated information that might be released subsequent to the CIRM's formal issuance of the RFP.

Proposals are due by 5:00p.m. on February 12, 2021.

In the opinion of the CIRM, this RFP is complete and without need of explanation. However, if prospective bidders have questions, notice any discrepancies or inconsistencies, or need any clarifying information, questions may be submitted to the CIRM no later than the date stated in Section C.1, Key Action Dates. Please note that no verbal information given will be binding upon the CIRM unless such information is issued in writing, as an official addendum, or as answers to bidders' written questions.

The contact person for this RFP is:

Chila Silva-Martin
Acting Contracts Administrator
California Institute for Regenerative Medicine
(415) 730-7418
contracts@cirm.ca.gov

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A. Purpose and Background

1. Purpose

The California Institute for Regenerative Medicine (CIRM) is requesting proposals from qualified independent public accounting and consulting firms for performance audit services. Health & Safety Code section 125290.30, subdivision (c) mandates that the CIRM commission a performance audit every three years beginning with the 2010-11 fiscal year. The performance audit for the 2019-2020 fiscal year will examine the functions, operations, management systems, and policies and procedures of the CIRM to assess whether it is achieving economy, efficiency, and effectiveness in the employment of available resources. In addition, the audit will examine whether the CIRM is complying with policies and procedures established by its governing board.

The focus of the performance audit is on the CIRM's process for grants award and administration, rather than the scientific goals and performance of the research funded by the grants. The statute specifically excludes scientific performance from the scope of the audit. The performance audit shall include all of the following:

- Policies and procedures for the issuance of contracts and a review of a representative sample of contracts;
- Policies and procedures for the issuance of grants and loans and a review of a representative sample of grants and loans; and
- Policies and procedures relating to the protection or treatment of intellectual property rights associated with research funded or commissioned by the CIRM.

2. Background

This section provides a high level summary of the CIRM functions and operations and is intended as background for prospective bidders to assist in their development of proposals to provide performance auditing services. **The following information should not be construed to be an exhaustive or comprehensive description of the CIRM's processes and activities.**

a. Overview of CIRM

CIRM's mission is to accelerate stem cell treatments to patients with unmet medical needs.

The California Institute for Regenerative Medicine (CIRM) arose from the vision of California's people: that stem cell treatments could provide new options and greater hope to patients with serious unmet medical needs. Patient advocates joined forces with doctors and scientists to create a vehicle to fund stem cell research in California.

On November 2, 2004, 59 percent of the voters in this state approved Proposition 71, which amended the California Constitution to establish the right to conduct stem cell research in California, authorized \$3 billion to fund stem cell research, and created the CIRM. In authorizing these funds, Californians expect to speed the development and delivery of stem cell treatments and cures to patients, including making it a priority to fund ethical research that was not receiving timely or sufficient federal funding. The CIRM's governing Board, the Independent Citizens' Oversight Committee (ICOC), continually works to further the CIRM's mission while providing financial responsibility to the people of California. The ICOC, which includes representatives from patient advocacy groups, medical research, and industry, is charged with adopting scientific, medical, ethical, and intellectual property policies; making final funding decisions on grant and loan awards; and providing oversight of the CIRM. The CIRM is focused on achieving its mission through the timely and efficient funding of high-quality stem cell projects and accelerating delivery of resulting treatments and cures to patients in need. The CIRM is singularly committed to this goal. This year, the voters approved Prop 14 which amends Prop 71 and allocates another 5.5 billion dollars to fund regenerative medicine research.

ICOC members are public officials, appointed on the basis of their experience earned in California's leading public universities, non-profit academic and research institutions, patient advocacy groups and the biotechnology industry. The ICOC members elect a chairperson and vice chairperson, who serve six-year terms and meet certain criteria also specified in the code.

The ICOC's functions are specified in Health and Safety Code section 125290.40 and include the following duties relevant to this performance audit:

- Develops annual long-term strategic research and financial plans;
- Makes final decisions on research standards and grant awards;
- Ensures completion of an annual financial audit;
- Establishes policies regarding intellectual property rights arising from research funded by the CIRM;
- Establishes rules and guidelines for the operation of the ICOC and its working groups; and
- Adopts, amends, and rescinds rules and regulations to carry out Proposition 71 and to govern the procedures of the ICOC.

Three scientific and medical working groups advise the ICOC but do not have final decision-making authority. They provide guidance related to ethical standards, grants review, and facilities as follows:

- The Scientific and Medical Accountability Standards Working Group (Standards Working Group), made up of patient advocate members of the ICOC, ethicists,

and clinicians, makes recommendations regarding medical and ethical standards for obtaining research materials and for the conduct of clinical trials.

- The Scientific and Medical Research Facilities Working Group (Facilities Working Group), made up of patient advocates from the ICOC and real estate specialists, makes recommendations regarding funding for buildings and capital equipment including the setting of milestones and timetables.
- The Scientific and Medical Research Funding Working Group (Grants Working Group), draws from over 200 stem cell science experts from outside California and from patient advocates on the ICOC, reviews applications for funding and makes recommendations as to which applications should be funded.

The President serves as the CIRM's President and Chief Executive Officer, and oversees the CIRM team. The President's primary responsibilities are to recruit the highest scientific and medical talent in the United States to serve on working groups; to serve the CIRM on its working groups; to direct the ICOC team and participate in the process of supporting all working group requirements to develop recommendations on grants, loans, facilities, and standards, as well as to direct and support the ICOC process of evaluating and acting on those recommendations; the implementation of all decisions on these and general matters of the ICOC; to hire, direct, and manage the team; to develop the budgets and cost control programs; to manage compliance with all rules and regulations of the ICOC, including the performance of all grant award recipients; and to manage and execute all intellectual property agreements and any other contracts pertaining to the CIRM or research it funds.

The CIRM has policies in place for its internal administrative procedures, regulations for its grant making activities, and procedures to be followed by awardees. All of the policies, procedures, and regulations will be provided to the successful bidder after the award of the contract.

b. Contracts

Although the CIRM is a State agency, Proposition 71 allowed it to adopt procurement policies based on University of California policies, which differ from other California State agencies. The CIRM's adopted contracting policies, which are based upon University of California Business and Finance Bulletin 34, can be found on the CIRM's website (see Appendix 2).

Approximately 120 contracts were issued during the 2019-20 fiscal year for services including independent consultants, hotel agreements, and support services, such as legal, accounting, and information technology. In addition, the CIRM issued approximately 40 Purchase Orders to procure goods and services paid through the State's Cal Card account, Citi meeting credit cards or warrants. The majority of these purchases are less than \$1,000.

The annual CIRM financial audit covers most of the accounting function, including formal testing of accounting transactions. The scope of the performance audit should not duplicate formal testing of accounting transactions currently performed by the financial auditor.

c. Grants Application, Review, and Approval

The CIRM's Portfolio Development and Review Office manages the application, review and approval process. The process is guided by Proposition 71, the Grants Administration Policy, and the Grants Working Group Bylaws. The CIRM offers recurring funding opportunities that are described under a Program Announcement (PA), and specific or ad hoc opportunities under a Request for Applications (RFA). The RFA or PA is the official document that specifies the objectives, applicable requirements, eligible costs, and the review criteria that will be used to evaluate the merits of applications submitted in response to the solicitation. Prior to issuing a solicitation, the concept for a funding opportunity must first be approved by the CIRM's Governing Board, the ICOC.

Applications submitted to the CIRM in response to a solicitation are screened for eligibility and then eligible applications are assigned to the Grants Working Group (GWG) to evaluate and score the applications based on scientific merit. Each application is reviewed in depth by two or three reviewers who comment on the overall scientific merit of the application under the specific review criteria defined in the RFA or PA. Review by the GWG follows the procedures described in the GWG Bylaws. The task of the GWG is to identify the most meritorious applications and make funding recommendations to the Governing Board.

The Application Review Subcommittee of the ICOC considers the recommendations of the GWG and conducts a programmatic assessment of the applications. The ICOC subcommittee may accept, reject, or modify the GWG recommendation for any application. The ICOC authorizes funding of the approved applications.

Table 1 provides information on the number of applications submitted, reviewed and approved in the 2019-2020 fiscal year.

Table 1: Annual Application Activity

Application Process	Funding Opportunity Program				
	Discovery	Translation	Clinical	Infrastructure	Education
Applications Submitted	55	8	32	0	4
Applications Reviewed	46	3	21	0	3
Applications Approved	10	1	8	0	3

During both the GWG and ICOC review processes, GWG and ICOC members must ensure they have no conflict-of-interest (COI) with any particular application. The CIRM team spends considerable time identifying potential COI issues. The CIRM generates a list from the Grants Management System (GMS) that captures the names of all individuals and organizations provided in grant applications as key personnel or subcontracts. GWG members, ICOC members, and the CIRM team members review the list and report any conflicts with the recorded names. The GMS matches the recorded names to associated applications. Based on reported conflicts, the CIRM team identifies recusals for GWG members, ICOC members, and the CIRM team members for each application. The GMS also identifies all GWG and ICOC members and their affiliations, which can be cross-referenced to the individuals and companies listed in the grant applications. The CIRM team checks the cross-references and notifies GWG and ICOC members when there are matches. In addition, if an application is discussed in a GWG review meeting, any member with a potential COI must leave the room during discussions. During ICOC review, ICOC members must abstain from discussing and voting on any applications for which they have a COI and leave the room during any closed session discussion of those applications.

d. Grants Management

The Grants Management Office is responsible for pre-award review, award acceptance, monitoring, payment and close-out processes. During the pre-award review phase, the team creates an award record for the approved applications. For each award, there is an assigned CIRM Grants Management Officer (GMO) and a Science Officer (SO). The GMO and SO conduct a Pre-Funding Administrative Review (PFAR) prior to funding an approved application. Both the GMO and SO utilize a PFAR checklist that details what they must review. During PFAR, the team verifies eligibility information in the grant application (i.e., confirm that the principal investigator possesses the academic degrees stated in the application), ensures that any approvals needed to start the project are in place as required by the CIRM's medical and ethical standards, develops milestones and a disbursement schedule, and checks for any other items needed to confirm the project is ready to launch. If the ICOC approves an application subject to conditions or modifications, the GMO and SO consult with the applicant on how to implement those changes. PFAR is concluded when both the GMO and SO have submitted their checklists.

During the Award Acceptance Phase, the CIRM team prepares the Notice of Award (NOA), which includes any special terms and/or any budget adjustments noted on the checklists. If needed, the CIRM Legal team also reviews the NOA. Following this review, a CIRM scientific executive reviews and signs the NOA via DocuSign and it is sent electronically to the Awardee for review and signature. Upon full execution of the NOA, the CIRM team processes the first payment via Electronic Funds Transfer (EFT) through the CIRM Grants Management System that is approved by the GMO and Finance Office then sent to the California State Controller's Office to process the payment. The State Controller's Office (SCO) either transfers fund electronically to the grantee or issues a warrant to release funds to the Awardee. After payment is issued, the SCO submits EFT

payment data to the CIRM for uploading to the Grants Management System and FI\$Cal, the CIRM's accounting system.

During the Monitoring Phase, the Awardee provides various progress and financial reports after the grant has been awarded. The reports contain different information depending on whether the award funded training, research, or facilities. CIRM's Grant Administration Policies (see Appendix 2) and the RFA document list the reporting requirements. The grant management activities for fiscal year 2019-20 are listed in Table 2.

Table 2: Grants Management Estimates for Fiscal Year 2019-20

Grants Management Process	Estimate for FY 2019-20
# of Pre-Funding Administrative Reviews	32
# of New Awards	
• Conference awards	2
• Research awards	30
• Research Training or Bridges to Research awards	0
• Facilities awards	0
# of Award Payments	267
# of Awardee Progress Reports Submitted	543
# of Awardee Financial Reports Submitted	499
# of Awards Closed-Out	221

e. Loans

Some CIRM-sponsored research projects are funded through loans rather than grants. Loans are limited to larger projects (at least \$3 million) undertaken by for-profit applicants. The Loans Administration Policy can be found on the CIRM's website (see Appendix 3). Most terms and processes for loans are the same as those for grants. The key difference is that a loan recipient has a conditional obligation to repay the CIRM funding, but is not subject to the revenue-sharing provisions of the Intellectual Property regulations. During the audit period, a grant was converted to a loan and the loan was repaid in full during the 19/20 FY audit period .

f. Grants Management System

The CIRM maintains a custom web-based Grants Management System (GMS) to support application submission, review, approval, and post-award processes.

g. Intellectual Property Policies

Proposition 71 authorized the ICOC to develop intellectual property (IP) policies to obtain a financial return to the State on the bond funding while assuring that essential medical research would not be unreasonably hindered. **The adequacy of the IP policies is outside the scope of this performance audit.**

Under the current IP policies (see Appendix 2), the CIRM does not own any inventions. However, awardee must notify the CIRM about any CIRM-funded inventions and share the resulting revenue. Within 60 calendar days after a CIRM-funded invention has been reported by the principal investigator to the awardee institution's IP/Technology Transfer Office, the awardee must submit an Invention Disclosure Form, which identifies the award, the inventor(s), and the principal investigator.

The awardee must undertake reasonable efforts to bring their inventions to practical use and to share revenue with the State of California based on formulas specified in the IP policies. In addition, if the awardee develops drugs or therapeutic treatments resulting in whole or in part from CIRM-funded research, the awardee must ensure access to eligible Californians and price protections for sales to State agencies and the California Discount Prescription Drug Program.

Awardees may publish their CIRM-funded finding in scientific journals, or publish an abstract in connection with a scientific meeting, information about a CIRM-funded invention, or a CIRM-funded technology. In the event of a publication, the awardee must submit a Publication Disclosure Form to the CIRM.

Awardees also must submit an Invention Utilization Report to the CIRM, which includes any patents, execution of license agreements, material transfer agreements or collaborative agreements, annually and for 15 years after the project period of the award. The elements of the Invention Utilization Report are defined in the IP policies.

B. Statement of Work

1. Services to be Provided

The selected bidder will conduct a performance audit of the CIRM's functions, operations, management systems, and policies and procedures for the 2019-20 fiscal year. The performance audit objectives and audit scope are defined in Health & Safety Code section 125290.30, subdivision (c). The performance audit will assess: 1) whether the CIRM is achieving economy, efficiency, and effectiveness in the employment of available resources; and 2) whether the CIRM is complying with ICOC policies and procedures.

The statute excludes a review of scientific performance from the scope of this audit.

The performance audit must be conducted in accordance with generally accepted government auditing standards (GAGAS) as defined by the General Accounting Office's (GAO) Governmental Auditing Standards (GAO Yellow Book).

2. Deliverables

a. Audit Plan

The auditor will develop a performance audit plan based on a comprehensive risk assessment model, developed by the auditor, which identifies in priority order the functions or operational areas to audit (i.e., CIRM functions and operational areas, in order of priority, that could be examined within the available audit budget in addition to the statutorily-defined examination of contracts, grants and loans, and intellectual property). The detailed audit plan will adhere to GAGAS and the GAO's Auditing Standards and provide the methodology the auditor will use to address the audit objectives. The audit plan will describe both the nature and extent of audit procedures to be used for gathering and analyzing evidence, including the specific steps and tests the auditors will perform. The auditor will design the audit methodology to obtain sufficient, appropriate evidence to address the audit objectives, reduce audit risk to an acceptable level, and provide reasonable assurance that the evidence is sufficient and appropriate to support the findings and conclusions. The plan will include the expected dates for completing field work for each audit objective.

b. Draft Report

The auditor will provide a written draft performance audit report that contains observations, conclusions, and actionable recommendations for the CIRM. The draft audit report must be fully supported with sufficient and appropriate evidence as required by the GAO's Government Auditing Standards. The auditor must communicate its findings, conclusions, and recommendations and provide CIRM management the opportunity to review and comment, per GAGAS.

c. Draft Final Report

The auditor will provide a written draft final performance audit report that contains observations, conclusions, and actionable recommendations for the CIRM. The draft final audit report must be fully supported with sufficient and appropriate evidence as required by the GAO's Government Auditing Standards and contain the following: 1) executive summary; 2) the objectives, scope, and methodology of the audit; 3) the audit results, including findings, conclusions, and recommendations, as appropriate; 4) a statement about the auditors' compliance with generally accepted government auditing standards; 5) a summary of the views of CIRM management regarding audit findings; and 6) if applicable, the nature of any confidential or sensitive information omitted. In addition, the auditor will create a presentation (i.e., PowerPoint) to convey the results of the audit and make the presentation to CIRM management.

d. Final Report

The auditor will submit a final audit report to CIRM management, including an executive summary and CIRM management's response to the recommendations. The auditor will provide a minimum of five hard copies and one electronic copy (on CD) of the final report. The auditor should also be prepared to make the presentation to the ICOC Governing Board or a designated subcommittee, and the Citizens Financial Accountability Oversight Committee (CFAOC) which may meet anywhere in California.

3. Performance Expectations

The CIRM has the following performance expectations of the auditor in providing these services. Note that any on-site review would need to be consistent with Alameda County COVID-19 guidelines in effect at that time.

The auditor must:

- Conduct all activities in accordance with the agreed upon contract terms and with the GAO's Governmental Auditing Standards.
- Be sensitive to the impact that requests for information or documentation have on the CIRM team's ability to carry out their normal duties and responsibilities.
- Work remotely to conduct interviews, collect evidence, conduct entrance and exit conferences, or carry out any other activities that require direct interaction with the CIRM team or direct examination of the CIRM documentation. Create secure modes of transferring important data remotely.
- Notify CIRM management prior to the release of the final draft audit report to the discovery of any significant issues per GAGAS. Prior to the release of the final draft report, the auditor will provide CIRM management an opportunity to explain its perspective on the issue and/or provide the necessary documentation or information.
- Maintain the strictest confidentiality regarding any issues relating to the audit's subject matter prior to the public release of the audit final report. Those within the CIRM must have a clear business need to know and those outside the CIRM must be authorized by law or regulation to receive the information. The auditor may contact other jurisdictions or agencies to obtain information where the contact is reasonable or necessary to complete the audit.
- Deliver all work products in a timely manner, with a goal of having the final report completed by August 27, 2021, with subsequent presentation to the ICOC.
- Communicate issues, findings, and recommendations clearly and succinctly. The CIRM values the discovery of significant issues and recommendations related to the audit objectives and scope. The quality of the issues raised and recommendations made is more important than the quantity.

4. Duration of Contract

The contract for these services will cover a period, starting in April 2021 and ending with a presentation to the ICOC in late summer/early fall 2021. The starting and ending dates may change if the CIRM makes an award earlier than expected or if the CIRM cannot execute the agreement in a timely manner due to unforeseen delays. The CIRM reserves the right to extend the term of the resulting agreement as necessary to complete or continue the services. Presentation to the CFAOC may occur after August 27, 2021.

5. Budget

Cost proposals must not exceed \$275,000.

C. Procurement Information

This section of the RFP contains the anticipated schedule for the procurement and describes the procurement events as well as the conditions governing the procurement.

1. Key Action Dates

Action	Time (if applicable)	Date
CIRM issues RFP		January 4, 2021
Bidders submit email of intent to bid	3:00 pm	January 15, 2021
Bidders submit written questions	3:00 pm	January 15, 2021
CIRM responds to written questions		January 22, 2021
Bidders submit proposals	5:00 pm	February 12, 2021
CIRM evaluates proposals*		February 17, 2021
CIRM selects finalists (at its sole discretion)*		March 1, 2021
CIRM conducts interviews (at its sole discretion)*	TBD	March 3-4, 2021.
CIRM notifies apparent successful bidder*		March 8, 2021.
Final negotiations, award contract		March 8-12, 2021.
Successful bidder commences work		April 1, 2021.

* These dates are subject to change at CIRM's sole discretion.

2. Explanation of Events

a. Issue RFP

This RFP has been issued by the California Institute for Regenerative Medicine. Copies of supporting this RFP, including documents, may be obtained from the CIRM's website at http://www.cirm.ca.gov/jobs_RFPs.

b. Submit Intent to Bid

All prospective bidders are encouraged to register their Intent to Bid as soon as possible after release of the RFP to provide greater assurance that they will receive written responses to questions or other notifications about this RFP. Requesting the RFP does not constitute submission of intent to bid. However, there is no penalty for not submitting an Intent to Bid. Any prospective bidder may pose written questions or submit a proposal even if they have not submitted an Intent to Bid.

To submit an Intent to Bid, prospective bidders should email their firm's name, person to contact, email address, mailing address, physical address, and daytime telephone number to Chila Silva-Martin at contracts@circ.ca.gov. In the subject line of the email, state the following: *Intent to Bid on RFP 20/21 CIRM 101: Your Firm's Name*.

c. Submit Written Questions

Potential bidders may submit written questions via email until 3:00p.m. PDT by the deadline to submit written questions, as indicated in Section C.1, Key Action Dates. The Contract Administrator will not respond to questions submitted in any other manner or format. Questions should be emailed to contracts@circ.ca.gov. In the subject line of the email, state the following: *Questions for RFP 20/21 CIRM 101: Your Firm's Name*.

When submitting a written question, bidders should provide the following information:

- Bidder's name, name of firm submitting the inquiry, mailing address, email address, area code and telephone number, and fax number;
- A description of the subject or issue in question or discrepancy found;
- RFP section, page number or other information useful in identifying the specific problem or issue in question; and
- Clarification sought, if any.

Bidders submitting inquiries by email are responsible for confirming the receipt of all materials by the deadlines, as indicated in Section C.1, Key Action Dates.. Call Chila Silva Martin at (415) 730-7418 to confirm email receipt.

Additional written requests for clarification of distributed answers and/or addendums must be received by the Contract Administrator no later than three (3) days after the answers and/or addendums are posted at http://www.cirm.ca.gov/Jobs_RFPs.

d. Response to Written Questions

The Contract Administrator will email written responses to all prospective bidders that submitted an Intent to Bid. In addition, the Contract Administrator will post written responses to written questions and any RFP amendments on the CIRM website at http://www.cirm.ca.gov/Jobs_RFPs. The CIRM reserves the right to post addenda until the RFP closing date and time.

e. Submission of Proposals

Proposals must be submitted in conformance with Section E, Proposal Format and Organization. No oral, telephone or facsimile proposals will be accepted. The CIRM personnel will not merge, collate, or assemble proposal materials.

A bidder may submit an amended proposal before the deadline for receipt of proposals. Such amended proposals must be complete replacements for a previously submitted proposal and must be clearly identified as such in the transmittal letter.

Proposals must be received electronically no later than the deadline specified in Section C.1, Key Action Dates, to the attention of the Contracts Administrator at the location listed below:

Chila Silva Martin
Acting Contracts Administrator
California Institute for Regenerative Medicine
contracts@cirm.ca.gov

f. Interviews of Finalists

At its sole discretion, the CIRM may require the highest ranked firms to make an oral presentation to the RFP Evaluation Committee. In the event finalists are interviewed, such oral presentations would be via teleconferencing due to COVID-19. The selected finalists will have an opportunity to summarize the information provided in their written proposals, expand on their capabilities, experience, proposed approach, work plan, and respond to questions from the RFP Evaluation Committee. It is important that the primary individuals assigned to the performance audit participate in the presentation and interview.

g. Final Negotiations and Contract Award

The finalist that provides the best value to the CIRM will be deemed the apparent successful bidder, subject to approval by the CIRM President. The CIRM may discuss with the apparent successful bidder any deficiencies or other aspects of its proposal such as price, technical approach, and terms that could, in the opinion of the CIRM, be altered or explained to enhance materially the apparent successful bidder's proposal. The scope and extent of discussions are a matter solely within the CIRM's judgment. If the CIRM and the apparent successful bidder cannot come to agreement on these alterations, the CIRM, at its sole discretion, may elect to hold discussions with the next ranked bidder.

Upon contract award, the performance auditor shall begin service immediately.

3. Conditions of the Procurement

a. CIRM Rights

The CIRM reserves the right to do the following at any time:

- 1) Reject any or all proposal(s), without indicating any reason for the rejection;
- 2) Waive or correct any minor or inadvertent defect, irregularity or technical error in a proposal or the RFP process, or as part of any subsequent contract negotiation;
- 3) Request that bidders supplement or modify all or certain aspects of their proposals or other documents or materials submitted;
- 4) Terminate the RFP and, at its option, issue a new RFP, or decline to reissue the RFP;
- 5) Extend a deadline specified in this RFP, including deadlines for accepting proposals;
- 6) Negotiate with any or none of the bidders;
- 7) Modify in the final agreement any terms and/or conditions described in this RFP;
- 8) Terminate failed negotiations with a bidder without liability, and negotiate with other bidders;
- 9) Disqualify any bidder on the basis of a real or apparent conflict of interest, or evidence of collusion that is disclosed by the proposal or other data available to the CIRM;
- 10) Eliminate, reject or disqualify a proposal of any bidder who is not a responsible bidder or fails to submit a responsive offer as determined solely by the CIRM;
- 11) Accept all or a portion of a bidder's proposal; and
- 12) Undertake any investigation, including, without limitation, contacting third parties, for assessing the background, experience, qualification and expertise of any or all bidders.

b. Bidders' Costs

Bidders are responsible for all costs of developing and submitting a proposal package, interviews, or any other bidder's costs associated with this solicitation. Such costs cannot be charged to the CIRM or included in any cost element of a bidder's price offering.

c. Contract Terms and Conditions

The bidder that is awarded a contract as a result of this procurement must comply with the terms, including insurance requirements, in the CIRM's standard Independent Consultant Agreement (see Appendix 1). The successful contractor must submit a Payee Data Record, Std. 204 (see Appendix 2.) All prospective bidders must indicate in the Proposal Transmittal Letter that they understand and will comply with the terms and conditions in the Independent Consultant Agreement.

d. Follow-on Work

The bidder that is awarded a contract as a result of this procurement is precluded from bidding on any subsequent contract or performing any follow-on work related to the findings and conclusions presented in the final performance audit report.

e. California Public Records Act

Under the California Public Records Act, the records of State agencies are generally available to the public upon request. A proposal that a bidder submits will be a public document. If a bidder is awarded a contract as a result of this procurement, the contract will be a public document.

The Public Records Act allows the CIRM to withhold documents, or parts of documents, that reveal trade secrets or information that is confidential or proprietary, or information that would invade personal privacy. Bidders should submit their proposals in a form that does not include such information. If a bidder wishes to include non-public information, the bidder should place that information in a separate envelope labeled "Confidential," and include a brief explanation of the reason the information is non-public. If a bidder does not provide an adequate basis for withholding the information, the CIRM is required to make it available to the public. The CIRM reserves the right to make the final determination whether to withhold or produce a document or portion of a document in response to a Public Records Act request. If the CIRM withholds information at the bidder's request, the bidder may be required to litigate any claim of trade secret asserted.

The CIRM is not permitted to provide legal advice about the Public Records Act and/or its exemptions. The following documents provide additional information about the CIRM's obligations under the Public Records Act:

- CIRM Public Records Access Guide
http://www.cirm.ca.gov/sites/default/files/files/about_cirm/guidelines.pdf
- Summary of the California Public Records Act
http://www.ag.ca.gov/publications/summary_public_records_act.pdf

D. Bidder Qualifications

The CIRM expects the auditor to demonstrate a high degree of experience, training and proficiency in the conduct of performance audits. The bidder should have extensive background in both performance auditing of governmental agencies and grants programs. Performance audit experience in the federal government, in California and other states, or in non-profit funding organizations may be considered as satisfying this requirement. In addition, the CIRM expects that the auditor will comply with GAGAS as defined in the GAO's Yellow Book and will maintain appropriate expertise at the firm's own expense. The bidder must meet, at a minimum, the following requirements:

- Firm must have an office established in the State of California.
- Firm must be licensed to do business in the State of California.
- Firm must have conducted within the last ten (10) years, at least three (3) performance audits or management reviews of governmental agencies, preferably agencies engaged in grants administration. Performance audit experience in the federal government, in California, and other states may be considered as satisfying this requirement. Performance audit experience with non-profit grant funding organizations would also be considered valuable.
- Firm must provide copies (hard-copy or electronic) of at least two (2) performance audit reports or management reviews that the firm has performed within the past ten (10) years in accordance with GAO Government Auditing Standards. The firm must have had primary responsibility for performing the majority of the work on each audit.
- Firm must agree to retain working papers and other performance audit work products for seven (7) years. In retaining these records, the firm should give appropriate consideration to the sensitivity of the information contained in the documents to prevent the unauthorized release of confidential information.
- Firm must have sufficient staff to provide to the CIRM the performance auditing services and deliverables described in Section B, Statement of Work.
- Firm must demonstrate that in all matters relating to the performance audit work, the audit organization and the individual auditor are free both in fact and appearance from personal, external and organizational impairments to independence.
- Firm must not be a publicly traded corporation, or subsidiary thereof, that is incorporated offshore, but for the public trading of the corporation's stock the principal market is the United States.
- Firm must be able to comply with the terms, including all of the insurance requirements, in the CIRM's standard Independent Consultant Agreement (see Appendix 1) and acknowledge compliance with these terms in the Proposal Transmittal Letter.

E. Proposal Format and Organization

1. Number of Copies

Bidders must submit two (2) copies of their proposal in Portable Document Format (PDF) to the location specified in Section C.2.e. All PDF documents submitted electronically by the Proposer to the CIRM must be free of viruses, encryption, malware and disablers. Proposers may provide electronic signatures on the required documents stated in Section E.f, Proposal Format & Organization, Required Attachments. Failure to comply may cause the Proposal to be rejected.

Procurement Information – Proposals must be submitted on or before the deadline for Bidders to submit proposals, as indicated in Section C.1, Key Action Dates. The original must be stamped “Original” and contain original signatures on the necessary forms. The remaining sets must be identical copies of the original.

2. Proposal Format

All proposals should be typewritten on standard 8 ½ x 11 paper (larger size paper is permissible for charts, spreadsheets, etc.) and placed within a binder with tabs delineating each section. Bidders should utilize both sides of the paper where practical.

a. Letter of Transmittal

The bidder must provide a Letter of Transmittal that contains the following elements:

1. A summary of the firm’s pertinent expertise, skills, client base and services provided.
2. A primary contact for the proposal, including the name, address, telephone numbers and email address.
3. Statement that if awarded the contract as the primary contractor, the bidder will accept full responsibility for successful performance of the entire scope of work.
4. Statement that the firm acknowledges and will comply with the terms, including all of the insurance requirements, in the CIRM’s standard Independent Consultant Agreement (see Appendix 1).

b. Experience and Qualifications of the Firm

This section of the proposal should demonstrate the bidder’s qualifications, experience and capacity to conduct this performance audit. Bidders must provide references and work samples to substantiate this experience. This section of the bidders’ proposals should include the following elements:

- 1) Provide Firm Information utilizing Attachment 1.

- 2) Provide the following information:
- Legal status of the firm (sole proprietorship, partnership, corporation, etc.) and the year the entity was organized to do business as the entity now exists.
 - If the firm, any principals of the firm, or any proposed subcontractor contracted with the CIRM during the past 48 months, describe the work and/or provide other information available to identify the contract.
 - If any employee of the firm or employee of proposed subcontractors was an employee of the CIRM during the past 24 months or is now an employee of the CIRM, identify the individual by name, job title or position held, hire date, and separation date (if applicable).
 - If the bidder, including any proposed subcontractors, has had a public sector contract terminated for default in the past three (3) years, describe such incident. Termination for default is defined as notice to stop performance due to the firm's nonperformance or poor performance. Bidders will submit full details of the terms for default, identify the other party (including the name, address, and phone number), and present the bidder's position on the matter. The CIRM will evaluate the facts and may, at its sole discretion, reject the proposal on the grounds of the past experience. If the bidder has experienced no such termination for default in the past three (3) years, so indicate.
- 3) Describe the bidder's organization, including main business location, office location from which bidders' staff will work on this performance audit, names of principals, number of employees, client base, areas of specialization and expertise, and any other information that will assist the RFP Evaluation Committee in formulating an opinion about the stability and strength of the firm and corporate status.
- 4) Describe how the bidder meets the minimum qualifications specified in Section D, Bidder Qualifications.
- 5) Describe recent and relevant experience (past ten (10) years) that the bidder and all subcontractors have in conducting performance audits or management reviews of government organizations, programs or activities, or other audit experience that will assist in the performance of this audit.
- 6) Utilizing the References Form (Attachment 2), provide a minimum of three (3) references that can be checked by the RFP Evaluation Committee.
- 7) Provide one (1) copy each (hard-copy or electronic) of at least two (2) performance audit reports or management reviews and that the firm has performed within the past ten (10) years in accordance with GAO Government

Auditing Standards. The firm must have had primary responsibility for performing the majority of the work on each audit.

c. Experience and Qualifications of Proposed Personnel

It is essential that assigned team members are committed for the duration of the audit and that reporting lines are clear. This section of bidders' proposals should include the following elements:

1. Provide an organizational chart indicating lines of authority for all key personnel, including subcontractors, who will be involved in the performance audit. On the organizational chart, bidders should clearly identify the lead individual assigned to work directly with CIRM management who has the authority to resolve any problems, issues, or concerns.
2. Provide a description of the proposed audit team structure and internal quality control system to be used during the course of the project, including any subcontractors. The bidder should indicate who within the firm's organization will have prime responsibility and final authority for all work products. The bidder must demonstrate its team structure meets the requirements of GAO Yellow Book general standards 3.69 through 3.71 for "Competence" and standard 3.72 for "Technical Knowledge." In addition, the bidder must demonstrate that its internal quality control system meets the requirements of general standards 3.82 pertaining to "Quality Control and Assurances" and 3.83 – 3.85 pertaining to "System of Quality Control."
3. Provide appropriate leadership, management skills, authority, and resources to guide this project. The assignment of a skilled project manager will play a large role in fulfilling the requirement. The bidder must provide a résumé for the project manager and include information on the individual's specific skills related to this project, education, experience, significant accomplishments and responsibilities assumed on other similar projects.
4. Identify responsibilities and roles of the key staff, including any subcontractors, who will be assigned to the project. Include any anticipated involvement of CIRM staff and describe their level of participation.
5. Demonstrate that all staff proposed meet the following:
 - Possess the knowledge of GAGAS applicable to this audit and the education, skills and experience to apply such knowledge to the audit being performed;
 - Possess general knowledge of the type of environment in which the CIRM operates and the subject matter under review;

- Possess the skills to communicate clearly and effectively both orally and in writing; and
 - Are free both in fact and appearance from personal, external and organizational impairments to independence in all matters relating to this performance audit.
6. Provide résumés for the named key team, which must include information on the individual's specific skills related to this project, education, experience, significant accomplishments, and responsibilities assumed on other projects, and any other pertinent information. Résumés for subcontractor personnel will clearly display the word "SUBCONTRACTOR" on the top of the first page.

d. Statement of Work Approach

The bidder's proposal must include a description of the bidder's overall approach and a high-level workplan for providing the services and deliverables indicated in Section B, Statement of Work.

Bidders are requested to not simply repeat the "Yellow Book" in their proposal. Please elaborate upon how your firm would apply the GAGAS and "Yellow Book" framework to produce the most relevant, actionable, and value-added performance audit report for the CIRM.

e. Cost Proposals

Proposers must fully complete Cost Detail Table (Attachment 3) that summarizes: 1) proposed cost per project team member, and 2) proposed cost per deliverable. The total project cost cannot exceed \$275,000. Note that the hourly rates must be fully loaded to include all professional fees, support services, travel, and any other expenses.

f. Required Attachments

- Firm Information (Attachment 1)
- References Form (Attachment 2)
- Cost Detail (Attachment 3)

g. Other Contents of Proposal

Bidders may include any relevant information and pertinent exhibits in the proposal. Proposals are to be prepared in such a way as to provide a straightforward, concise delineation of capabilities to satisfy the requirements of this RFP. Emphasis should be on conformance to the instructions and responsiveness to the requirements described herein, and on completeness and clarity of content.

F. Proposal Evaluation

Proposals must be complete in all respects and submitted by the dates and times shown in Section C.1, Key Action Dates. A proposal may, at the sole discretion of the CIRM, be rejected if it is conditional, incomplete, or it contains any alterations of form or other irregularities.

The selection of a firm to perform the requested services will be made by a CIRM-appointed RFP Evaluation Committee that will evaluate proposals in accordance with the evaluation criteria and weighted factors specified in Table 3 and establish a ranking. The maximum points available for each criterion are also noted in Table 3. A serious deficiency in any one criterion may be grounds for rejection. The CIRM shall have the right to obtain, from any and all sources, information concerning a bidder, which is deemed pertinent to this RFP, and to consider such information in the evaluation of the bidder's proposal.

Table 3: Evaluation Criteria

Criteria	Maximum Points
Completeness, clarity and Succinctness of Proposal	10
Experience and Qualifications of the Firm	40
Experience and Qualifications of Proposed Staff	50
Approach and Methodology	30
Work Samples	30
Cost	40
Maximum Total Possible Points:	200

The listing of cost as an evaluation factor does not require the CIRM to select the firm that submits the lowest price. The CIRM intends to select the proposal which provides the best value. A proposal meeting the requirements of the RFP with the lowest price may not be selected if award to a higher priced proposal, in the judgment of the RFP Evaluation Committee, maximizes greater overall benefits to the CIRM. The CIRM may elect to pay a higher price to select a proposal that overall is exceptional and reasonably priced. The RFP Evaluation Committee will assess each component in the bidder's cost detail in relation to the services the bidder offers. A bidder that exceeds the requirements by providing more services, higher quality services, or more experienced staff for a reasonable price will receive the highest consideration.

The CIRM reserves the right to select the top ranked firm based solely on the scoring of the written proposals and to enter directly into negotiations with said firm. However, at its sole discretion, the CIRM may contact the references of the highest ranked firms and require the highest ranked firms to make an oral presentation to the RFP Evaluation Committee. In this event, oral presentations will be scheduled via Zoom. Selected

finalists will have an opportunity to summarize the information provided in their written proposals, expand on their capabilities, experience, proposed approach and work plan and answer questions from the RFP Evaluation Committee. It is important that the primary individuals servicing the contract are present for this presentation.

Upon completion of the oral presentations, the RFP Evaluation Committee will review the material presented and determine a ranking order for the firms interviewed. Negotiations will be conducted with the highest ranked firm until a contract is awarded. If an agreement cannot be reached on contract terms, negotiations will be terminated and the next highest ranked firm will be contacted for negotiations.

List of Attachments

Attachment 1: Firm Information

Attachment 2: References Form

Attachment 3: Cost Detail

Attachment 1: Firm Information

Name of firm or individual
proposed consultant

Business or trade name, if
different from above

Business Form
(check only one)

- ☐ Corporation
☐ Partnership
☐ LLC
☐ Individual/Sole Proprietor
☐ Other: _____

Mailing Address

City

State

Zip

Website

Firm Contact
Name

Email

Telephone

Fax

Total dollar amount of consultant work that the firm has
performed for the CIRM in the last 12 months.

The name and position of any CIRM employee who holds a position of director,
officer, partner, trustee, manager or employee in the consultant organization, as well
as the names of any near relatives who are employed by the CIRM.

Certification

I hereby certify under penalty of perjury that I am authorized by the proposed
consultant to submit this proposal on its behalf. I have reviewed all
information provided in the accompanying proposal, and it is true and
complete to the best of my knowledge.

Signature

Date

Name

Title

Attachment 2: References Form

Proposers must provide the following client information for at least three (3) prior performance audits of similar size and scope. Provide the name, title, telephone number, and email of contact persons that the CIRM may contact to inquire about your firm's performance. The references should be individuals who: 1) were project leaders; 2) can validate your firm's role and responsibilities; and 3) can comment on the quality of your firm's performance.

REFERENCE CLIENT #1

Client Name	
Client Address	
Contact Name	
Contact Title	
Contact Phone #	
Contact Email	
Project Name	
Project Start/End Dates	
Project Description	
Project Budget	

REFERENCE CLIENT #2

Client Name	
Client Address	
Contact Name	
Contact Title	
Contact Phone #	
Contact Email	
Project Name	
Project Start/End Dates	
Project Description	
Project Budget	

REFERENCE CLIENT #3

Client Name	
Client Address	
Contact Name	
Contact Title	
Contact Phone #	
Contact Email	
Project Name	
Project Start/End Dates	
Project Description	
Project Budget	

Attachment 3: Cost Detail

Proposers must fully complete the following cost tables that summarize: 1) proposed cost per project staff member, and 2) proposed cost per deliverable. The total project cost cannot exceed \$275,000. Note that the hourly rates must be fully loaded to include all professional fees, support services, travel, and any other expenses.

Table A – Cost per Staff Member

Staff Name	Project Role	(a) Rate per Hour	(b) Total Hours	(a) x (b) Staff Total Cost
Total Cost:				

Table B – Cost per Deliverable

<i>Deliverable 1 – Audit Plan</i>				
Staff Name	Project Role	(a) Rate per Hour	(b) Total Hours	(a) x (b) Staff Total Cost
Total Cost for Deliverable 1:				
<i>Deliverable 2 – Draft Report</i>				
Staff Name	Project Role	(a) Rate per Hour	(b) Total Hours	(a) x (b) Staff Total Cost
Total Cost for Deliverable 2:				
<i>Deliverable 3 – Draft Final Report</i>				
Staff Name	Project Role	(a) Rate per Hour	(b) Total Hours	(a) x (b) Staff Total Cost
Total Cost for Deliverable 3:				
<i>Deliverable 4 – Final Report</i>				
Staff Name	Project Role	(a) Rate per Hour	(b) Total Hours	(a) x (b) Staff Total Cost
Total Cost for Deliverable 4:				

List of Appendices

Appendix 1: Independent Consultant Agreement

Appendix 2: Payee Data Record (State Standard Form 204)

Appendix 3: Links to the CIRM's Policies and Regulations

Appendix 1: Independent Consultant Agreement

Agreement No. CIRM _____

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE INDEPENDENT CONSULTANT AGREEMENT

THIS AGREEMENT to furnish certain consultant services is made by and between the California Institute for Regenerative Medicine hereinafter called (CIRM), and _____[Name]_____ (Consultant).

I. NATURE AND PLACE(S) OF SERVICE

- A. The Consultant shall furnish to CIRM the following described services including a time schedule by which the Consultant is to produce or provide specified materials or perform certain consulting services as well as reports on the progress of the services:

- i. See attachment A.

- B. If the Consultant is an entity other than an individual, CIRM requires that staff be assigned according to Attachment A to perform the work set forth herein. No reassignment of work to individuals other than those described in Attachment A may be made without the written approval of CIRM.

- C. Place(s) of performance of such services shall be:

Consultant's location:

$$\begin{bmatrix} \vdots \\ \vdots \\ \vdots \end{bmatrix}$$

CIRM's location:

1999 Harrison Street, Suite 1650
Oakland, CA 94612

- D. CIRM will provide working space, equipment, furniture, utilities, and services, as follows:

II. TERM OF AGREEMENT

- A. The term of this Agreement shall be from _____ through _____.

- B. CIRM reserves the right to terminate this Agreement subject to 30 days written notice to the Consultant. Consultant may submit a written notice to terminate this Agreement only if CIRM should substantially fail to perform its responsibilities as provided herein. In addition, CIRM may terminate this Agreement immediately for cause. The term “for cause” shall mean that the Consultant fails to meet the terms, conditions, and/or responsibilities of this Agreement. In this instance, the termination shall be effective as of the date indicated on CIRM’s notification to the Consultant.

- C. The term of this Agreement may be extended by the mutual, written consent of both parties.

III. COMPENSATION AND REIMBURSEMENT FOR EXPENSES

A. CIRM shall pay the Consultant for services performed on the following basis:

1. Professional Fees:

2. Other Expenses

MAXIMUM TO BE PAID UNDER THIS AGREEMENT

\$ _____

* Reimbursement for travel and per diem shall be in accordance with established CIRM rates and policies.

B. Payments shall be made upon the Consultant's submission of invoices indicating the Agreement Number and setting forth charges in accordance with rates detailed in Article III-A. Consultant must submit a completed Payee Data Record (State Standard Form 204) before CIRM will issue payment. Each invoice shall include the Consultant's taxpayer identification number (Social Security or employer identification number). Invoices shall be submitted not more frequently than monthly in arrears to:

California Institute for Regenerative Medicine
accountspayable@cirm.ca.gov
Finance Officer
1999 Harrison Street, Suite 1650
Oakland, CA 94612

Payment will be made in accordance with, and within the time specified in, Government Code Chapter 4.5, commencing with Section 927.

IV. REPORTING

In performing consulting services under this Agreement, the Consultant shall be accountable to CIRM and shall provide progress reports to CIRM upon CIRM's request.

V. NOTIFICATION

Notices concerning this Agreement shall be addressed as follows:

CIRM:

TO CONSULTANT:

California Institute for Regenerative Medicine
General Counsel
1999 Harrison Street, Suite 1650
Oakland, CA 94612

VI. TAXES

The compensation stated in Article III includes all applicable taxes and will not be changed hereafter as the result of Consultant's failure to include any applicable tax or as the result of any change in the Consultant's tax liabilities. The Consultant acknowledges that compensation payable hereunder may be subject to withholding of state and federal income tax, including state income tax subject to withholding pursuant to California Revenue and Taxation Code Sections 18661-18677.

VII. INDEPENDENT CONTRACTOR STATUS

- A. Both parties agree that in the performance of this Agreement the Consultant shall not be an agent or employee of CIRM, shall not be covered by the State's Worker's Compensation Insurance or Unemployment Insurance, shall not be eligible to participate in State employee retirement programs, and shall not be entitled to any other CIRM employee benefits.
- B. The Consultant shall be solely responsible for the conduct and control of the work to be performed by the Consultant under this Agreement, except that the Consultant is accountable to CIRM for the results of such work. The Consultant's services for CIRM shall be performed in accordance with currently approved methods and ethical standards applicable to the Consultant's professional capacity.
- C. California State Contract Code 10515 (a) states: No person, firm, or subsidiary thereof who has been awarded a consulting services contract may submit a bid for, nor be awarded a contract on or after July 1, 2003, for the provision of services, procurement of goods or supplies, or any other related action that is required, suggested, or otherwise deemed appropriate in the end product of the consulting services contract.

VIII. ASSIGNMENT OR SUBCONTRACTING

The Consultant may not assign or transfer this Agreement, or any interest or claim, or subcontract any portion of the work, without the prior written approval of CIRM. The withholding or granting of such approval is totally discretionary with CIRM. If CIRM consents to such assignment or transfer, the terms and conditions of this Agreement shall be binding upon any assignee or transferee.

IX. PROPERTY RIGHTS, INCLUDING PATENTS AND COPYRIGHTS

All written and other tangible material ("Material") produced pursuant to this Agreement by the Consultant shall be considered a work-made-for-hire under the Copyright Act. To the extent said Material does not qualify as a work-made-for-hire, Consultant hereby assigns all right, title, and interest, including, but not limited to, copyright and all copyright rights in the Material to CIRM and shall execute any and all documents necessary to effectuate such assignment. In the event Consultant uses any individual who is not a full-time employee of Consultant or uses any other entity to perform any of the work required by Consultant hereunder, Consultant shall require said individual or entity to sign an agreement before commencing work that contains identical wording to the foregoing two sentences except that the word "Consultant" shall be replaced with the individual's or entity's name.

X. CONSULTANT'S LIABILITY AND INSURANCE REQUIREMENTS

- A. The Consultant agrees to defend and, at CIRM's election, indemnify and hold harmless CIRM, its officers, agents, and employees from and against any and all claims, losses, expenses (including costs and reasonable attorney's fees), claims for injury, or damages that are caused by or result from the negligent or intentional acts or omissions or breach of this Agreement by the Consultant or its officers, employees, or agents. In addition, Consultant agrees to defend and, at CIRM's election, indemnify, and hold harmless CIRM, its officers, agents, and employees from and against any and all claims, losses, expenses (including costs and reasonable attorney's fees), claims for injury, or damages accruing or resulting to any and all contractors, subcontractors, suppliers, or any other person, firm or corporation furnishing services or supplying goods in connection with Consultant's performance of this Agreement
- B. The Consultant shall furnish a Certificate of Insurance or statement of self-insurance (contractual liability included) showing minimum coverage as follows:

1. General Liability: Comprehensive or Commercial Form (Minimum Limits)

(i) General Aggregate (BI, PD)*	\$2,000,000
(ii) Products, Completed Operations Aggregate	\$2,000,000
(iii) Personal and Advertising Injury	\$1,000,000
(iv) Each Occurrence	\$1,000,000

* (not applicable to comprehensive form)

However, if such insurance is written on a claims-made form following termination of this Agreement, coverage shall survive for a period no less than three years. Coverage must include a Primary and Non-Contributory provision and a Severability of Interest provision. Coverage shall also provide for a retroactive date of placement coinciding with the effective date of this Agreement.

2. Business Auto Liability: (Minimum Limits) for Owned, Scheduled, Non-Owned, or Hired Automobiles with a combined single limit of no less than \$1,000,000 per occurrence. [Alternative: Business Auto Liability is waived because Consultant will not drive in the course of performing services for CIRM.]

3. Workers' Compensation: as required under California State Law.

4. Professional Liability Insurance: (Minimum Limits)

(1) Each occurrence	\$2,000,000
(2) Project Aggregate	\$2,000,000

If this insurance is written on a claims-made form, it shall continue for three years following termination of this Agreement. The insurance shall have a retroactive date of placement prior to or coinciding with the effective date of this Agreement. The insurance must include Contractual Liability Coverage and Defense and Indemnification of CIRM by the contracting party.

5. Other insurance in amounts as from time to time may reasonably be required by the mutual consent of CIRM and the Consultant against such other insurable hazards relating to performance.

6. Certificate(s) of Insurance shall name CIRM as an additional insured under 1, 2 and 4 above, obligate the insurer to notify CIRM at least thirty (30) days prior to cancellation of or changes in any of the required insurance and include a provision that the coverage will be primary and will not participate with nor be excess to any valid and collectible insurance program of self-insurance carried or maintained by CIRM. Premiums on all insurance policies shall be paid directly by the Consultant.

XI. RECORDS ABOUT INDIVIDUALS

- A. The Consultant acknowledges that the creation and maintenance of records pertaining to individuals is subject to certain requirements set forth by the California Information Practices Act (Civil Code 1798, et seq.) and by CIRM policy. Such requirements include provisions governing the collection, maintenance, accuracy, dissemination, and disclosure of information about individuals, including the right of access by the subject individuals.
- B. If the Consultant creates confidential or personal records about an individual, as defined by the Information Practices Act, including notes or tape recordings, the information shall be

collected to the greatest extent practicable directly from the individual who is the subject of the information. When collecting the information, the Consultant shall inform the individual that the record is being made and of the purpose of the record.

- C. Records containing confidential or personal information about individuals are the property of CIRM and subject to CIRM's policies and applicable federal and state laws. The Consultant agrees to deliver all such records, including originals and all copies and summaries, to CIRM upon termination of this Agreement.
- D. The Consultant shall not use recording devices in discussions with CIRM's employees without notifying all parties to the discussion that the discussion is being recorded.

XII. EXAMINATION OF RECORDS

The Consultant agrees that CIRM and its authorized agents shall have the right to review and copy any records and supporting documentation pertaining to the performance of this Agreement including, but not limited to, all documents, records and work papers whether obtained or copied from CIRM or developed by the Consultant. Consultant agrees to maintain such records for a minimum of five (5) years after final payment, unless a longer period of records retention is stipulated. Consultant agrees to allow CIRM and its authorized agent's access to such records during normal business hours. Further, Consultant agrees to include a similar right of access in any subcontract related to the performance of this Agreement.

In accordance with state law, the Consultant agrees that CIRM, its authorized agents, the State Controller's Office, and the Bureau of State Audits (collectively, the "Auditors") shall have the right, in connection with an audit, to review and copy any records and supporting documentation pertaining to the performance of this Agreement including, but not limited to, all documents, records and work papers whether obtained or copied from CIRM or developed by the Consultant. Consultant agrees to maintain such records for possible audit for a minimum of five (5) years after final payment, unless a longer period of records retention is stipulated. Consultant agrees to allow the Auditors access to such records during normal business hours and to allow interviews of any employees who might reasonably have information related to such records. Further, Consultant agrees to include a similar right of the Auditors to audit records and interview team in any subcontract related to the performance of this Agreement.

XIII. CONFLICT OF INTEREST

- A. The Consultant will not hire any officer or employee of CIRM to perform any service covered by this Agreement. If the work is to be performed in connection with a federal or state contract or grant, the Consultant will not hire any employee of the government agency concerned to perform any service covered by this Agreement.
- B. The Consultant affirms that to the best of his/her knowledge there exists no actual or potential conflict between the Consultant's family, business or financial interest and the services provided under this Agreement, and in the event of change in either private interests or service under this Agreement, any question regarding possible conflict of interest which may arise as a result of such change will be raised with CIRM.
- C. The Consultant shall not be in a reporting relationship to a CIRM employee who is a near relative, nor shall the near relative be in a decision-making position with respect to the Consultant.
- D. The Consultant may be required to execute a Form 700 Statement of Economic Interests as published by the Fair Political Practices Commission. Statements of Economic Interests are public documents. More information about Form 700 is available at www.fppc.ca.gov.

XIV. AFFIRMATIVE ACTION

The Consultant recognizes that as a state government contractor or subcontractor, the Consultant is obligated to comply with all state laws and regulations regarding equal opportunity and affirmative action in government contracts. When applicable, the Consultant agrees that all such laws and their implementing regulations are incorporated herein as though set forth in full. These laws include the nondiscrimination requirements of Government Code sections 12990 and 11135, and the nondiscrimination program and clause required by Title 2, Division 4, Chapter 5 of the California Code of Regulations.

XV. CONFIDENTIALITY

The Consultant shall keep confidential any and all information provided by CIRM, and/or by a CIRM awardee, including by any of their agents or representatives, and any information conveyed orally to the Consultant by CIRM and/or by a CIRM awardee, including any of their agents or representatives, with oral notification of its confidentiality (the "Confidential Information"). The Consultant agrees to maintain the secrecy of CIRM's Confidential Information and agrees not to use it except in performing the Services under this Agreement and not to disclose it to anyone outside CIRM or anyone within CIRM's organization who does not have a need to know it to perform under this Agreement. This non-disclosure provision shall not apply to any of the following:

1. Information which the Consultant can demonstrate by written records was known to him or her prior to the effective date of this Agreement;
2. Is currently in, or in the future enters, the public domain other than through a breach of this Agreement or through other acts or omissions of the Consultant; or
3. Is obtained lawfully from a third party.

XVI. APPLICABLE LAW

The laws of the State of California shall govern this Agreement.

XVII. TERMS TO BE EXCLUSIVE

This Agreement constitutes the entire understanding between the parties regarding the subject matter hereof and supersedes any prior understanding between the parties, oral or written, regarding the same subject matter.

XVIII. WAIVER OR MODIFICATION OF TERMS

No waiver, amendment or other modifications of the terms of this Agreement shall be binding upon either party unless expressed in writing and signed by both parties hereto.

XIX. STANDARD FOR PERFORMANCE

The parties acknowledge that CIRM, in selecting the Consultant to perform the services hereunder, is relying upon the Consultant's reputation for excellence in the performance of the services required hereunder. The Consultant shall perform the services in the manner of one who is a recognized specialist in the types of services to be performed. All deadlines set forth in the Agreement are binding and may be modified only by subsequent written agreement of the parties. The Consultant shall devote such time to performance of its, her, or his duties under this Agreement as is reasonably necessary for the satisfactory performance of such duties within the deadlines set forth herein. Nothing in the foregoing shall be construed to alter the requirement that time is of the essence in this Agreement.

XX. EXCLUSION.

Independent Consultant warrants that it is not excluded from participation in any governmental sponsored program, including, without limitation, the Medicare, Medicaid, or Champus programs (<http://exclusions.oig.hhs.gov/search.aspx>) and the Federal Procurement and Nonprocurement Programs (<http://www.epls.gov/eplsearch.do>). This Agreement shall be subject to immediate termination in the event that the Independent Consultant is excluded from participation in any federal healthcare or procurement program.

XXI RESOLUTION OF DISPUTES

If the Consultant disputes any action by CIRM arising under or out of the performance of this contract, the Consultant shall notify CIRM of the dispute in writing and request a claims decision. CIRM shall issue a decision within 30 days of the Consultant's notice. If the Consultant disagrees with CIRM's claims decision, the Consultant shall submit a formal claim to the President of CIRM. The decision by the President of CIRM shall be final and conclusive on the claim unless the decision is arbitrary, capricious or grossly erroneous or if any determination of fact is unsupported by substantial evidence. The decision may encompass facts, interpretation of the contract and determinations or applications of law. The decision shall be in writing following an opportunity for the Consultant to present oral or documentary evidence and arguments in support of the claim. Consultant shall continue with the responsibilities under this Agreement during any dispute.

XXII SURVIVAL.

The following sections survive the expiration or early termination of this Agreement: IX, X, XI, XII, XV, XVI, XXI and XXII.

INDEPENDENT CONSULTANT

THE CALIFORNIA INSTITUTE FOR
REGENERATIVE MEDICINE

Signature Date

Date

Name _____

Title _____

Company _____

Item 6445-502-6047001/H&S Code 125291.20/Statutes 2004/ FY 20/21
Account/Fund to be charged

Appendix 2: Payee Data Record

STATE OF CALIFORNIA-DEPARTMENT OF FINANCE

PAYEE DATA RECORD

(Required when receiving payment from the State of California in lieu of IRS W-9 or W-7)
STD 204 (Rev. 10/2019)

1	INSTRUCTIONS: Type or print the information. Complete all information on this form. Sign, date, and return to the state agency (department/office) address shown in Box 6. Prompt return of this fully completed form will prevent delays when processing payments. Information provided in this form will be used by California state agencies to prepare Information Returns (Form1099). See next page for more information and Privacy Statement. NOTE: Governmental entities, i.e. federal, state, and local (including school districts), are not required to submit this form.					
2	BUSINESS NAME <small>(As shown on your income tax return)</small> <hr/> <div style="display: flex; justify-content: space-between;"> <div style="width: 65%;"> SOLE PROPRIETOR, SINGLE MEMBER LLC, INDIVIDUAL <small>(Name as shown on SSN or ITIN) Last, First, MI</small> </div> <div style="width: 30%;"> E-MAIL ADDRESS </div> </div> <hr/> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> MAILING ADDRESS <hr/> <div style="display: flex; justify-content: space-between;"> <div style="width: 30%;">CITY</div> <div style="width: 10%;">STATE</div> <div style="width: 20%;">ZIP CODE</div> </div> </div> <div style="width: 45%;"> BUSINESS ADDRESS <hr/> <div style="display: flex; justify-content: space-between;"> <div style="width: 30%;">CITY</div> <div style="width: 10%;">STATE</div> <div style="width: 20%;">ZIP CODE</div> </div> </div> </div>					
3	<div style="display: flex; justify-content: space-between;"> <div style="width: 75%;"> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> ENTER FEDERAL EMPLOYER IDENTIFICATION NUMBER (FEIN): </div> <div style="width: 5%;">+</div> <div style="width: 45%;"> </div> </div> <div style="margin-top: 5px;"> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <input type="checkbox"/> PARTNERSHIP <input type="checkbox"/> ESTATE OR TRUST </div> <div style="width: 50%;"> CORPORATION: <input type="radio"/> MEDICAL <small>(e.g., dentistry, psychotherapy, chiropractic, etc.)</small> <input type="radio"/> LEGAL <small>(e.g., attorney services)</small> <input type="radio"/> EXEMPT <small>(nonprofit)</small> <input type="radio"/> ALL OTHERS </div> </div> </div> </div> <div style="width: 20%; vertical-align: top;"> NOTE: Payment will not be processed without an accompanying taxpayer identification number. </div> </div> <hr/> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <input type="checkbox"/> SOLE PROPRIETOR, INDIVIDUAL, OR SINGLE MEMBER LLC <small>(Disregarded Entity)</small> </div> <div style="width: 50%;"> ENTER SSN OR ITIN: </div> </div> <p style="font-size: small; margin-top: 5px;"><i>Social Security Number (SSN) or Individual Taxpayer Identification Number (ITIN) are required by authority of California Revenue and Tax Code sections 18646 and 18661</i></p>					
4	<div style="display: flex; justify-content: space-between;"> <div style="width: 20%;"> PAYEE RESIDENCY STATUS </div> <div style="width: 80%;"> <input type="checkbox"/> CALIFORNIA RESIDENT - Qualified to do business in California or maintains a permanent place of business in California. <input type="checkbox"/> CALIFORNIA NON RESIDENT <small>(see next page for more information)</small> - Payments to nonresidents for services may be subject to state income tax withholding. <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <input type="radio"/> No services performed in California. </div> <div style="width: 55%;"> <input type="radio"/> Copy of Franchise Tax Board waiver of state withholding attached. </div> </div> </div> </div>					
5	I hereby certify under penalty of perjury that the information provided on this document is true and correct. Should my residency status change, I will promptly notify the state agency below.					
AUTHORIZED PAYEE REPRESENTATIVE'S NAME <small>(Type or Print)</small>		TITLE		TELEPHONE <small>(include area code)</small>		
SIGNATURE		DATE		E-MAIL ADDRESS		
6	Please return completed form to:					
DEPARTMENT/OFFICE California Institute for Regenerative Medicine			UNIT/SECTION Finance			
MAILING ADDRESS			TELEPHONE <small>(include area code)</small> 415-740-8621		FAX 510-990-3857	
CITY		STATE	ZIP CODE		E-MAIL ADDRESS sthomison@cirm.ca.gov	

PAYEE DATA RECORD

(Required when receiving payment from the State of California in lieu of IRS W-9 or W-7)

STD 204 (Rev. 10/2019)

1	<p>Requirement to Complete the Payee Data Record, STD 204</p> <p>A completed Payee Data Record, STD 204 form, is required for all payees (non-governmental entities or individuals) entering into a transaction that may lead to a payment from the state. Each state agency requires a completed, signed, and dated STD 204 on file; therefore, it is possible for you to receive this form from multiple state agencies with which you do business.</p> <p>Payees who do not wish to complete the STD 204 may elect not to do business with the state. If the payee does not complete the STD 204 and the required payee data is not otherwise provided, payment may be reduced for federal and state backup withholding. Amounts reported on Information Returns (Form 1099) are in accordance with the Internal Revenue Code (IRC) and the California Revenue and Taxation Code (R&TC).</p>
2	<p>Enter the payee's legal business name. The name must match the name on the payee's tax return as filed with the federal Internal Revenue Service. Sole proprietorships and single member limited liability companies (LLCs) must also include the owner's full name. An individual must list his/her full name as shown on the SSN or as entered on the W-7 form for ITIN.</p> <p>The mailing address should be the address at which the payee chooses to receive correspondence. The business address is the address of the business' physical location.</p>
3	<p>Check only one box that corresponds to the payee business type. Corporations must check the box that identifies the type of corporation.</p> <p>The State of California requires that all parties entering into business transactions that may lead to payment(s) from the state provide their Taxpayer Identification Number (TIN). The TIN is required by the R&TC sections 18646 and 18661 to facilitate tax compliance enforcement activities and the preparation of Form 1099 and other information returns as required by the IRC section 6109(a) and R&TC section 18662 and its regulations.</p> <p>Payees must provide one of the following TINs on this form: social security number (SSN), individual taxpayer identification number (ITIN), or federal employer identification number (FEIN). The TIN for sole proprietorships, single member LLC (disregarded entities), and individuals is the SSN or ITIN. Only partnerships, estates, trusts, corporations, and LLCs (taxed as partnerships or corporations) will enter their FEIN.</p>
4	<p>Are you a California resident or nonresident?</p> <p>A corporation will be defined as a "resident" if it has a permanent place of business in California or is qualified through the Secretary of State to do business in California.</p> <p>A partnership is considered a resident partnership if it has a permanent place of business in California. An estate is a resident if the decedent was a California resident at time of death. A trust is a resident if at least one trustee is a California resident.</p> <p>For individuals and sole proprietors, the term "resident" includes every individual who is in California for other than a temporary or transitory purpose and any individual domiciled in California who is absent for a temporary or transitory purpose. Generally, an individual who comes to California for a purpose that will extend over a long or indefinite period will be considered a resident. However, an individual who comes to perform a particular contract of short duration will be considered a nonresident.</p> <p>Payments to all nonresidents may be subject to withholding. Nonresident payees performing services in California or receiving rent, lease, or royalty payments from property (real or personal) located in California will have 7% of their total payments withheld for state income taxes. However, no withholding is required if total payments to the payee are \$1,500 or less for the calendar year.</p> <p>For information on Nonresident Withholding, contact the Franchise Tax Board at the numbers listed below: Withholding Services and Compliance Section: 1-888-792-4900 E-mail address: wscs.gen@ftb.ca.gov For hearing impaired with TDD, call: 1-800-822-6268 Website: www.ftb.ca.gov</p>
5	Provide the name, title, email address, signature, and telephone number of the individual completing this form. Provide the date the form was completed.
6	This section must be completed by the state agency requesting the STD 204.

Privacy Statement

Section 7(b) of the Privacy Act of 1974 (Public Law 93-579) requires that any federal, state, or local governmental agency, which requests an individual to disclose their social security account number, shall inform that individual whether that disclosure is mandatory or voluntary, by which statutory or other authority such number is solicited, and what uses will be made of it.

It is mandatory to furnish the information requested. Federal law requires that payment for which the requested information is not provided is subject to federal backup withholding and state law imposes noncompliance penalties of up to \$20,000.

You have the right to access records containing your personal information, such as your SSN. To exercise that right, please contact the business services unit or the accounts payable unit of the state agency(ies) with which you transact that business.

All questions should be referred to the requesting state agency listed on the bottom front of this form.

Appendix 3: Links to the CIRM's Policies and Regulations

Contracts Policy

http://www.cirm.ca.gov/sites/default/files/files/about_cirm/Contracting_Policy_Adopted_20100819.pdf

Grants Administration Policy

<http://www.cirm.ca.gov/our-funding/chapter-5-grants-administration-policies>

Loan Administration Policy

<http://www.cirm.ca.gov/our-funding/chapter-8-loan-administration-policy>

Intellectual Property Regulations

Intellectual Property Requirements for Non-Profit organizations, applicable to grants made before December 17, 2009

<http://www.cirm.ca.gov/our-funding/chapter-3-intellectual-property-requirements-non-profit-organizations-applicable-grants>

Intellectual Property and Revenue Sharing Requirements for For-Profit organizations, applicable to grants made before December 17, 2009

<http://www.cirm.ca.gov/our-funding/chapter-4>

Intellectual Property and Revenue Sharing Requirements, applicable to grants made before January 27, 2014:

<http://www.cirm.ca.gov/our-funding/chapter-6-intellectual-property-and-revenue-sharing-requirements-non-profit-and-profit>

Intellectual Property and Revenue Sharing Requirements, effective January 27, 2014:

http://www.cirm.ca.gov/sites/default/files/files/funding_page/Reg100600_100611_27_January_2014.pdf